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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,232	09/05/2000	Stewart M. Kume	SMP0179US02	7770
28075	7590	10/03/2005		
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			EXAMINER MENDEZ, MANUEL A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Thin

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/655,232		KUME, STEWART M.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Manuel Mendez		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-9, 13-21 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-9, 13-21 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

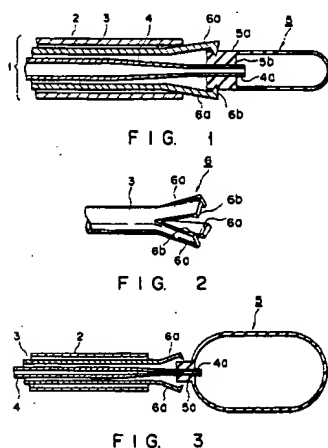
- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>09/29/2005</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 6-9, 13-21, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishida, et al., in view of Tanabe et al., and Becker et al.**



Ishida et al., shows an elongate catheter body, an expandable member attached to a distal end of the catheter body; and opaque markers positioned on the expandable member. In column 4, line 19, the specification states: "the material of the balloon (5) may be mixed with X-ray opaque substance such as platinum, gold or the like which constitutes a marker".

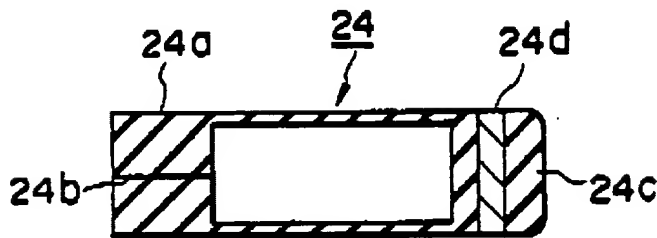


FIG. 11

Moreover, in column 6, line 55, referring to figure 11, the specification states: "the distal portion (24c) of the balloon (24) may be made solid, and a belt-type marker (24d) made of x-ray opaque substance as described above may be fixed to or embedded in the outer peripheral surface portion (24c)". Based on the teachings of Ishida et al., the use of markers in a balloon is conventional in the art. However, the applicant discloses a plurality of markers arranged in a pattern.

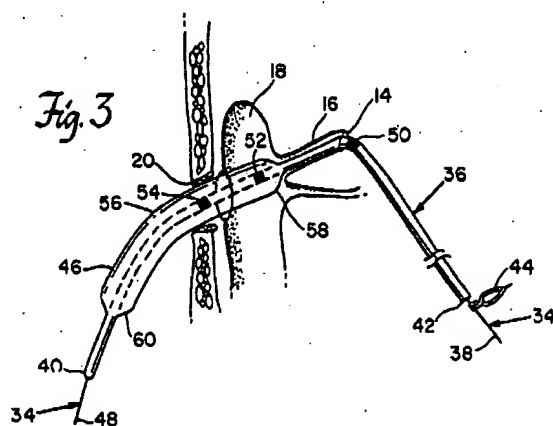
Importantly, even do Ishida et al., does not disclose a plurality of markers, it is well established in case law that the mere duplication of a well known element (opaque markers) in an apparatus does not constitute patentable subject matter. Moreover, in this particular case, the use of opaque markers in a catheter arranged in a particular pattern is well known in the art as evidenced by Tanabe et al.

Therefore, for a person of ordinary skill in the art, modifying the balloon disclosed by Ishida et al., with multiple markers arranged in a pattern would have been considered obvious because such configuration would have enhanced the capabilities of the

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catheter system and the accuracy of localizing the catheter after deployment to the body.

Finally, neither Ishida et al., nor Tanabe et al., teach the use of ink as a marker. However, the use of ink as a marker is conventional in the art as evidenced by the teachings of Becker, et al.



The Becker, et al., Patent demonstrates in figure 3 (above), that it is conventional in the art to use ink as a marker (50) in the outer wall of a catheter. Accordingly, based on the teachings of the cited patents, it would have been obvious for a person of ordinary skill in the art to enhance or modify the structure Ishida et al., with the use of ink as a marker in the outer surface of any portion of the catheter including the inflatable balloon.

### **Conclusion**

In view of the new rejection, this action is not final. Any inquiry concerning this communication or earlier communications from the examiner should be directed to

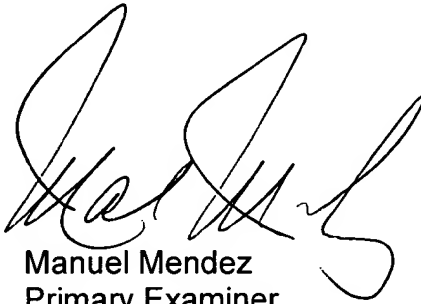
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Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,



Manuel Mendez  
Primary Examiner  
Art Unit 3763